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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,293	06/25/2003	Samuel Davis	REG 330G1Z	3258

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EXAMINER	
MERTZ, PREMA MARIA	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 08/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/603,293	DAVIS ET AL.	
	Examiner	Art Unit	
	Prema M. Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *76-79,81-83, 99 and 100* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *76-79,81-83,99 and 100* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/25/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-75, have been previously canceled. Claims 80, 84-98 have been canceled in the amendment of 7/12/2005. Claims 76-79, 81-83, 99-100 are pending in the instant application.

Election/Restrictions

1. Applicant's election of Group I (claims 76-79, 81-83, 99-100) in the reply filed on 7/12/2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 76-79, 81-83, 99-100 are under consideration by the Examiner.

Specification

2a. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. It is suggested that the title be amended to recite "a nucleic acid encoding TIE-2 ligand".

2b. It is clear from the declaration that Applicants intend to claim priority to the earlier filed applications. If applicant desires priority under 35 U.S.C. 120, specific reference to the earlier filed applications must be made in the instant application as "Cross Reference to Related Applications". This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of non-provisional application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No._____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Claim Rejections - 35 USC § 112, second paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 81-83 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 81, line 1, is rejected as vague and indefinite because of the limitation "....polypeptide which comprises the vector...". It is unclear whether the host-vector system or the polypeptide comprises the vector. For clarity, it is suggested that the claim be amended to recite "...polypeptide wherein the host-vector system comprises the vector...".

Claims 82-83 are rejected as vague and indefinite insofar as they depend on claim 81 for the above rejected limitation.

Claim rejections-Double Patenting

Non-statutory double patenting rejection (obviousness-type)

4. The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and 8 may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 76-79, 81-83, 99-100 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 5,814,464 in view of Capon et al. (U.S. Patent No. 5,116,964).

Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 76-79, 81-83 in the instant application claim "an isolated nucleic acid comprising the fibrinogen-like domain of human TIE-2 ligand consisting of nucleotides 1197-1844 of SEQ ID NO:5, a vector, a host cell, a method of producing the polypeptide and a chimeric molecule further comprising a nucleic acid encoding an immunoglobulin constant region". Claims 1-11 of U.S. Patent No. 5, 814,464 (having two common inventors with the instant application), claims "an isolated nucleic acid comprising SEQ ID NO:5, a vector, a host cell and a method of producing the polypeptide". It is clear that the claims differ in scope. Therefore, the instant claims are generic to claims 1-11 in the patent and encompasses subject matter to which allowed claims in the patent is a species. The instant claims are obvious from the patented claims because the instant claims are directed to specific embodiments encompassed by the patented claims. The instant products are included in the patented claims. However, the

patented product fails to teach a nucleic acid comprising a nucleic acid encoding TIE-2 ligand and further comprising a nucleic acid encoding immunoglobulin constant region (the polypeptide to which the encoded human TIE-2 ligand is bonded).

Capon et al. teaches chimeric proteins for directing ligand binding partners such as growth factors, hormones or effector molecules to cells bearing ligands for the ligand binding partners comprising a ligand binding partner fused to a stable plasma protein which is capable of extending the in vivo half-life of the ligand binding partner when present as a fusion with the ligand binding partner, in particular wherein such a stable plasma protein is an immunoglobulin constant domain (see column 4, lines 57-64; column 5, lines 11-21; column 7, lines 11-27; column 8, lines 13-15).

Therefore, it would have been prima facie obvious to one having ordinary skill in the art to modify the nucleic acid encoding the TIE-2 polypeptide of US Pat No. '464 such that it includes the nucleic acid bonded to a nucleic acid encoding the immunoglobulin constant region to obtain a chimeric protein with an increased circulating half-life, as taught by Capon et al., to obtain the known functions and advantages of TIE-2 ligand as per the teachings of US Pat No. '464. Cytokines such as TIE-2 ligand are well-known in the art as having a short half-life. One would have been motivated to obtain a nucleic acid encoding a chimeric protein comprising TIE-2 ligand and immunoglobulin constant domain to decrease the clearance rate of the encoded chimera *in vivo*. Therefore, it would have been obvious to fuse the nucleic acid encoding TIE-2 ligand to the nucleic acid encoding immunoglobulin constant domain, a long-lived molecule well known in the art as able to increase the stability of rapidly cleared molecules.

The patented claims if infringed upon would also result in infringement of the broad claim of the instant application. Allowance of the pending claim, therefore, would have the effect of extending the enforceable life of the allowed claims beyond the statutory limit.

Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz

Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
July 21, 2005